

### **REMARKS**

This paper is presented in response to the official action dated June 17, 2008, wherein (a) claims 84-141 were pending, (b) claims 88-141 were withdrawn from consideration, (c) claims 84, 85, and 87 were rejected under 35 USC 102 as being anticipated by Harris, et al. U.S. 6,187,765 ("Harris"), and (d) claim 86 was rejected under 35 USC 103 as obvious over Harris. This paper is further being supplied in response to the Notice of Non-Compliant Amendment, dated January 16, 2009.

With this paper, claims 84 and 86 are amended, claims 88-141 are canceled, and new claims 142-149 are added. Claim 84 has been amended to recite features of original claims 89 and 91. New claim 142 finds support in original claim 106. New claim 143 finds support in original claim 117. New claim 144 finds support in original claim 120. New claim 145 finds support in original claim 90. New claim 146 finds support in original claim 93. New claim 147 finds support in original claim 95. New claim 148 finds support in original claim 103. New claim 149 finds support in original claims 84, 91, and 106.

It is submitted that no new matter is introduced with this amendment. Claims 84-87 and 142-149 are pending. No additional claims fee is required.

#### ***Rejection of Claims 84, 85, and 87 Under 35 USC 102***

Claims 84, 85, and 87 stand rejected as anticipated by Harris. Applicants traverse and offer the following remarks. Reconsideration is requested.

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987). Thus, a determination that a claim is anticipated under 35 USC § 102 involves two analytical steps. First, the U.S. Patent and Trademark Office (PTO) must interpret the claim language, where necessary, to ascertain its meaning and scope. In interpreting the claim language, the PTO is permitted to attribute to the claims only their broadest reasonable meaning as understood by persons having ordinary skill in the art, considered in view of the entire disclosure of the

specification. See *In re Morris*, 127 F.3d 1048, 1054 (Fed. Cir. 1997). Second, the PTO must compare the construed claim to a single prior art reference and set forth factual findings that “each and every limitation is found either expressly or inherently [disclosed] in [that] single prior art reference.” *Celeritas Techs. Ltd. v. Rockwell Int’l Corp.*, 150 F.3d 1354, 1360 (Fed. Cir. 1998). Additionally, “[t]he identical invention must be shown in as complete detail as is contained in the patent claim.” *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236 (Fed. Cir. 1989).

Harris fails to disclose each element of the pending claims. The Patent Office cites to column 7 of Harris to support its anticipation rejection, indicating that Harris, “discloses in column 7 the passing of a sterilized suspension through a sterilized microfluidizer” (Action at p. 2). However, Harris at column 7 is silent regarding a using an apparatus having the recited features of a conduit having a sterilizable diaphragm needle valve, as recited in the rejected claims.

Harris also fails to disclose each element of new independent claim 149. Claim 149 recites a method that comprises sterilizing a particle size reduction apparatus by passing steam or water through a sterilizable diaphragm needle valve and through a bushing assembly. Thus, Harris cannot anticipate the pending claims, and this rejection should be withdrawn. Such action is solicited.

### ***Rejection of Claim 86 Under 35 USC 103***

Claim 86 stands rejected as unpatentable over Harris. The applicants traverse and offer the following remarks. Reconsideration is requested.

A determination that a claimed invention is obvious under § 103(a) is a legal conclusion involving four factual inquiries: (1) the scope and content of the prior art; (2) the differences between the claimed invention and the prior art; (3) the level of ordinary skill in the pertinent art; and (4) secondary considerations, if any, of non-obviousness. *Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966). Secondary considerations of non-obviousness include factors such as commercial success, long-felt but unresolved needs, the failure of others, and/or unexpected results achieved by the claimed invention. *Id.* Obviousness is determined from the vantage point of a hypothetical person having ordinary skill in the art to which the claimed

subject matter pertains, who is presumed to have all prior art references in the field of the invention available to him/her. *In re Rouffet*, 149 F.3d 1350, 1357 (Fed. Cir. 1998). Furthermore, obviousness must be determined as of the time the invention was made and in view of the state of the art that existed at that time. *Uniroyal, Inc. v. Rudkin-Wiley Corp.*, 837 F.2d 1044, 1050-51 (Fed. Cir. 1988).

The Patent Office “has the burden under § 103 to establish a prima facie case of obviousness.” *In re Fine*, 837 F.2d 1071, 1074 (Fed. Cir. 1988); MPEP § 2142 (8<sup>th</sup> Ed., Rev. 6, Sept. 2007) (“The examiner bears the initial burden of factually supporting any prima facie conclusion of obviousness.”). The Supreme Court recently identified a number of rationales that may be used to support a conclusion of obviousness, consistent with the framework set forth in its decision in *Graham v. John Deere. Co. See KSR Int’l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1739-40 (2007). These and other representative rationales are described at MPEP § 2143 (8<sup>th</sup> Ed., Rev. 6, Sept. 2007). Regardless of the supporting rationale, however, the Patent Office must clearly articulate facts and reasons why the claimed invention “as a whole” would have been obvious to a hypothetical person having ordinary skill in the art at least as of the claimed invention’s effective filing date. *See KSR Int’l*, 127 S.Ct. at 1741 (citing with approval *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006) (“[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.”)); *see also* MPEP § 2143 (“The key to supporting any rejection under 35 USC § 103 is the clear articulation of reason(s) why the claimed invention would have been obvious.”).

The action does not clearly articulate facts and reasons why the claimed invention “as a whole” would have been obvious to a hypothetical person having ordinary skill in the art at least as of the claimed invention’s effective filing date. Specifically, the action does not articulate findings of fact relating to (1) the scope and content of the prior art, (2) the differences between the claimed invention and the prior art, and, (3) the level of ordinary skill in the pertinent art. Still further, while the action appears to rationalize its conclusion of obviousness, the action does not articulate facts sufficient to support the asserted rationale. *See* MPEP § 2143.

The action, therefore, does not set forth a prima facie case of obviousness. Accordingly, the applicant respectfully traverses the rejection, and requests reconsideration and withdrawal of the rejection.

Independent claim 84 recites a method of producing a comminuted sterile suspension of particles comprising subjecting an initial sterile suspension of particles to a comminution procedure carried out in a sterilized particle size reduction apparatus having (i) an interaction chamber, (ii) an intensifier, and (iii) a conduit between the two, the conduit having a sterilizable diaphragm needle valve. Dependent claims 142-148 recite additional features such as that the intensifier further comprises a reciprocating plunger and bushing assembly with a channel to allow steam or water to pass to aid in sterilization. Harris fails to disclose an apparatus having a sterilizable diaphragm needle valve, reciprocating plunger, or bushing assembly.

The Patent Office has not identified a rationale as to why an apparatus as recited in claim 86 (or any of the other pending claims) would be obvious in view of Harris, as Harris fails to provide any motivation to modify its teachings to arrive at the claimed method. There is no suggestion in Harris to modify the method in the currently claimed manner – that is to use a sterilizable diaphragm needle valve (independent claim 84) or to sterilize the apparatus by passing steam through the diaphragm needle valve and bushing assembly (independent claim 149). The applicants have invented a method for producing sterile suspensions of particles that either allows for sterilization or recites a sterilization step during the process, and does not necessarily require using pre-sterilized components.

The Patent Office has alleged that, with respect to claim 86, it would have been an “obvious design choice” to have a method which produced a comminuted sterile suspension of particles having the specific particle dimensions of 2  $\mu\text{m}$  to 3  $\mu\text{m}$ . However, the Patent Office cites to no authority for this allegation. Accordingly, the applicant respectfully requests that the Patent Office clearly identify the authority on which it relies for its allegation.

In view of the foregoing, the applicants respectfully request reconsideration and withdrawal of the outstanding rejections, and allowance of all pending claims.

***Conclusion***

In view of the above amendments and remarks, the applicants believe the application is in condition for allowance.

Should the examiner wish to discuss the foregoing, or any matter of form in an effort to advance this application toward allowance, he is urged to telephone the undersigned at the indicated number.

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Respectfully submitted,  
Electronic signature: /Shelley C. Danek,  
Reg. #57,712/  
Shelley C. Danek  
Registration No. 57,712  
MARSHALL, GERSTEIN & BORUN LLP  
6300 Sears Tower  
233 South Wacker Drive  
Chicago, Illinois 60606-6357  
(312) 474-6300  
Agent for Applicants